

## **REMARKS**

### ***Status of Claims***

Claims 1, 2, 7, 13, 16, and 29 have been amended and claims 22-23 have been canceled. No other claim has been added, amended, or canceled, and no new matter has been added. Upon entry of the claim amendments, claims 1-13, 16-21, 24-26, 29, and 31 will remain in the application.

### ***Interview Summary***

Applicant appreciates the courtesies extended by Examiner Ketter during a telephonic interview with Applicant's undersigned representative on June 21, 2010. During the interview, proposed claim amendments for overcoming the objections and rejections were discussed. Examiner Ketter generally agreed that the proposed amendments would overcome the rejections but that he would need to reconsider and consult with his supervisor before committing to allowance. Further consideration is requested.

### ***Claim Objections Under 37 CFR 1.75(c)***

Claims 2 and 13 are objected to under 37 CFR 1.75(c) as allegedly being of improper dependent form for allegedly failing to further limit the subject matter of a previous claim. In particular, claims 2 and 13 are objected to as they allegedly "encompass variants of several of the recited parameters of the parent claim" and "encompass some of said parameters outside of the ranges in the parent claim" and thus present a larger scope than the claims from which they depend. Claims 2 and 13 have been amended to obviate this objection by incorporating the ranges for the parameters as set forth in claims 1 and 7 from which these claims respectively depend. Claims 2 and 13 thus do not expand the scope of the claims from which they depend. Withdrawal of the objection to claims 2 and 13 is solicited.

### ***Claim Rejections – 35 U.S.C. §102(b)***

Claims 16-21, 26, and 29 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by WO 01/62336 ("Brighton") or US Patent No. 4,600,010 ("Dugot"). These rejections are traversed.

Independent claims 16 and 29 have been amended to specify that the signal source controls and varies "duration of time of application of said at least one specific and selective signal for a predetermined duration of time from approximately ½ hour to 24 hours per 24

hour period at a predetermined duty cycle from approximately 10%-100%” so as to selectively up-regulate the gene expression of BMP-2, BMP-4, BMP-5, BMP-6, and/or BMP-7 in the targeted tissue as measured by mRNA as a result of application of the specific and selective field in the targeted tissue. These features are nowhere shown or suggested by Brighton or Dugot.

In particular, neither Brighton nor Dugot provides a signal source with means for controlling and varying the duty cycle of the at least one specific and selective signal applied to the field generating device “from approximately 10% to 100% so as to selectively up-regulate gene expression of BMP-2 (or BMP-4, BMP-5, BMP-6, and/or BMP-7) in the target tissue as measured by mRNA as a result of application of the specific and selective field in the targeted tissue” as claimed. This is distinct from turning on and off the device as taught by Dugot, which relates to the duration of application of the signal or the interval between applications. In other words, Dugot teaches varying the duration of application of the signal by turning the device on and off but does not teach varying the duty cycle as claimed. Also, Dugot did not teach a “specific and selective signal” as claimed and neither Dugot nor Brighton taught means for varying the duty cycle of such signal to “selectively up-regulate” gene expression of a BMP gene in the injured or diseased tissue as claimed. Absent such teachings, the rejections over these references cannot be maintained. Withdrawal of the rejections of claims 16-21, 26, and 29 as being anticipated by Brighton or Dugot is solicited.

***Claim Rejections – 35 U.S.C. §112, First Paragraph***

Claims 2, 13, 22, and 23 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 22 and 23 have been canceled, thereby obviating these rejections with respect to claims 22 and 23. These rejections as applied to claims 2 and 13 are respectfully traversed.

As noted above, claims 2 and 13 have been amended to incorporate the ranges for the parameters as set forth in claims 1 and 7 from which these claims respectively depend. In particular, the ranges for the signal characteristics have been amended to be commensurate with the scope of the ranges described in the specification. Accordingly, claims 2 and 13 do not vary the signals “in an unlimited fashion” as the examiner alleges. Withdrawal of the rejections of claims 2 and 13 is appropriate and is solicited.

***Claim Rejections – 35 U.S.C. §112, Second Paragraph***

Claims 1-13, 16-23, 26, and 29 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, independent claims 1, 7, 16, and 29 are rejected because the term “predetermined duration” is deemed to be indefinite. These claims have been amended to clarify that the “predetermined duration” is a “predetermined duration of time from approximately ½ hour to 24 hours per 24 hour period.” As “predetermined” is clearly understood by those skilled in the art to mean “to determine beforehand,” and inasmuch as the “predetermined duration” is disclosed at least in paragraphs [0012] and [0028] of the specification, the term “predetermined duration” as now set forth in the claims is believed to be quite clear and definite. Withdrawal of the rejection of claims 1-13, 16-23, 26, and 29 as being indefinite is solicited.

Also, claims 2 and 13 are rejected as indefinite for using the relative term “substantially.” The term “substantially” has been removed from claims 2 and 13, thereby obviating this rejection. Withdrawal of the rejection of claims 2 and 13 as being indefinite is solicited.

#### ***Allowed Claims***

Applicant appreciates the examiner’s indication that claims 24, 25, and 31 are allowed. For the reasons noted herein, all pending claims are now believed to be allowable.

#### **CONCLUSION**

Applicant respectfully submits that claims 1-13, 16-21, 24-26, 29, and 31 as amended are in condition for allowance. Early and favorable consideration is earnestly solicited. Moreover, if the Examiner does not find the present response sufficient to overcome any of the outstanding rejections, the Examiner is encouraged to contact the undersigned attorney to discuss suitable claim language for overcoming the rejection.

The Commissioner is also hereby authorized to charge any fee deficiency, charge any additional fees, or credit any overpayment of fees, associated with this application in connection with this filing, or any future filing, submitted to the U.S. Patent and Trademark Office during the pendency of this application, to Deposit Account No. 23-3050.

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